Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
*Governor*

Judith A. Monroe, M.D.
*State Health Commissioner*

**DATE:** August 21, 2009

**TO:** All Local Health Departments
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

ASG

**SUBJECT:** Nutracoastal Trading LLC Expanded Recall

**SUGGESTED ACTION:** **Unclassified Recall; Lot 90260 contains Tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making STEAM DIETARY SUPPLEMENT an unapproved drug; Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The recalled product listed below was distributed in white plastic bottles to retail stores nationwide. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.**

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## Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## Nutracoastal Trading LLC Expands Its voluntary nationwide recall of Steam Dietary supplement

**Contact:**
David McLoughlin
(866) 803-2434

**FOR IMMEDIATE RELEASE** – Freeport, NY – August 21, 2009 – Nutracoastal Trading LLC announced today that it is expanding its July 28th, 2009 voluntary nationwide recall of the company's dietary supplement product sold under the following name: **STEAM**.

The Company has found by lab analysis that **Lot 90260** contains Tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making **STEAM DIETARY SUPPLEMENT** an unapproved drug. The active drug ingredient is not listed on the product label. The undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

The recalled product listed below was distributed in white plastic bottles to retail stores nationwide.

| **Brand** Name | **Size** | **Lot** | **EXP.** | **UPC** |
|---|---|---|---|---|
| STEAM | 1 Bottle – 5 Capsules | 90260 | 6 11 | 8 52263 30033 1 |

No illnesses have been reported to the company to date in connection with this product.

Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

The FDA has been apprised of this action.

Nutracoastal Trading LLC, a Delaware Limited Liability Company, is committed to providing accurate information about its products because of concerns for the health and safety of consumers. It sincerely regrets any inconvenience to customers.

Consumers should return any unused product to the retail location where they were purchased or contact Nutracoastal Trading LLC directly at 866-803-2434 Monday – Friday, 9 am to 5 pm EDT.

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Photos: Product Labels